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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,164	11/26/2003	Stephan R. Targan	67789-711	8299

50670 7590 11/13/2007

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EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	**PAPER NUMBER**
1644	

MAIL DATE	DELIVERY MODE
11/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/723,164	TARGAN ET AL.	
	Examiner	Art Unit	
	Nora M. Rooney	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25,26 and 29-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-26 and 29-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2007 has been entered.

2. Claims 25-26 and 29-36 are pending and currently under consideration as they read on a method of determining a risk of having or developing a clinical subtype of Crohn's disease characterized by fibrostenosis, internal perforating disease or the need for small bowel surgery in a subject having Crohn's disease, comprising determining the presence or absence of three markers in the subject, said three markers being IgA anti-I2 antibodies, anti-Saccharomyces cerevisiae antibodies (ASCA), and IgA anti-OmpC antibodies.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 25-26 and 29-31 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Targan et al. (PTO-892, Reference U) in view of Vasiliauskas et al. (Reference 30, IDS filed on 11/03/2004) and Landers et al. (Reference 17, IDS filed on 11/03/2004) for the same reasons as set forth in the Office Action mailed on 01/29/2007.

Applicant's arguments submitted on 10/31/2007 have been fully considered, but are not found persuasive.

Applicants argue that Targan, et al., in view of Vasiliauskas, et al. and Landers, et al., does not anticipate the present application. Applicants submit that Targan, et al. only teaches that patients with seroreactivity to bacterial components, namely the OmpC and I2 markers, might be more likely to achieve antibiotic-induced remission to Crohn's Disease as compared to those who do not have expression of such markers. As the described antibodies are known to be produced in response to components of specific bacteria, the Targan, et al. reference merely suggests that an appropriate antibiotic therapy for an individual might be determined through the detection of antibodies of a corresponding bacterial component. Like Targan, et al., the present invention pertains to the determination of anti-I2, ASCA and anti-OmpC IgA molecules; however, unlike the cited reference, the present invention describes these markers in relation to their associations with specific Crohn's Disease subgroups, such as fibrostenosis. The invention as claimed goes beyond merely suggesting that bacterial component antibodies OmpC and I2 can be used to determine candidates for antibiotic therapy, and instead describes seroreactivity, including also

that of ASCA, that can be stratified into specific Crohn's Disease subgroups. One of skill in the art could not make these same associations based only on the results described by the reference. Furthermore, the Targan, et al. reference itself does not conclusively determine a correlation between seroreactivity and the likelihood of success for a particular antibiotic therapy, noting that trials of a more diverse cohort with antibiotics alone are required to corroborate their preliminary findings.

It is the Examiner's position that Targan, et al., in view of Vasiliauskas, et al. and Landers, et al. does make the instant claims obvious, contrary to Applicant's assertion. Targan et al. describes a sub-type of Crohn's disease patients: those patients whose Crohn's disease is associated with antibodies to bacteria (OmpC and I2 antibodies) who would benefit from antibiotics to kill those bacteria. Whether the Targan, et al. reference conclusively determines a correlation between seroreactivity and the likelihood of success for a particular antibiotic therapy is not persuasive. Targan et al. is being relied on simply for it's teaching that a subset of Crohn's disease patients has the serological markers I2 and OmpC. Applicant's argument that unlike the cited reference, the present invention describes these markers in relation to their associations with specific Crohn's Disease subgroups, such as fibrostenosis is not persuasive. Vasiliauskas et al. teaches detecting ASCA and ANCA antibodies as a tool to stratify Crohn's disease into immunologically homogenous subgroups with distinct characteristic including fibrostenosis, internal perforating disease and the need for small bowel surgery. It would be obvious to one of ordinary skill in the art at the time of invention to further combine the OmpC and I2 markers to further stratify the fibrostenotic subgroups, especially given the fact that some types of Crohn's

disease are associated with other bacterial markers as taught by Targan et al. and Landers et al. Further, Landers et al. and Vasilauskas et al. both teach using statistical analysis including Quartile analysis in particular as taught by Landers et al. to stratify patients based upon their serological marker phenotypes.

Applicant's argument that "One of skill in the art could not make these same associations based only on the results described by the reference" is unpersuasive. As described above, one of ordinary skill in the art could arrive at the claimed invention given the reasoning set forth by the Examiner in the Office Action mailed on 01/29/2007. The Examiner only needs to set forth a logical reason to combine the references. The reason to combine references need not be explicitly taught in the prior art, nor does the argument need to be for the same reasons that the Applicant used to invent.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 25-26 and 29-36 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention for the same reasons as set forth in the Office Action mailed on 07/25/2007. This is a New Matter rejection.

Applicant's arguments submitted on 10/31/2007 have been fully considered, but are not found persuasive.

Applicants submit that support for such a method is given throughout the instant specification on page 86, lines 1-29 and page 68, lines 27-30, page 72, lines 7-14, and page 75, lines 17-20.

It is the Examiner's position that Applicant has provided no support for the limitations at issue in the priority document, Application 10/413,501. Applicant has merely pointed to the instant specification for support. The instant claims now recite limitations which were not clearly disclosed in the specification and recited in the claims as originally filed in the 10/413,501 application priority document.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A

message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 5, 2007

Nora M. Rooney, M.S., J.D.

Patent Examiner

Technology Center 1600

Maher M. Haddad

MAHER M. HADDAD
PRIMARY EXAMINER